4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0190]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Infant Formula Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to https://www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review - Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910-0256. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Infant Formula Requirements--21 CFR parts 106 and 107

Statutory requirements for infant formula under the Federal Food, Drug, and Cosmetic Act (FD&C Act) are intended to protect the health of infants and include a number of reporting and recordkeeping requirements. Among other things, section 412 of the FD&C Act (21 U.S.C. 350a) requires manufacturers of infant formula to establish and adhere to quality control procedures, notify us when infant formula that has left the manufacturers' control may be adulterated or misbranded, and keep records of distribution. We have issued regulations to implement the FD&C Act's requirements for infant formula in parts 106 and 107 (21 CFR parts 106 and 107). We also regulate the labeling of infant formula under the authority of section 403 of the FD&C Act (21 U.S.C. 343). Under our labeling regulations for infant formula in part 107, the label of an infant formula must include nutrient information and directions for use. Failure to comply with any of the applicable labeling regulations will render an infant formula misbranded under section 403 of the FD&C Act. The purpose of these labeling requirements is to ensure that consumers have the information they need to prepare and use infant formula appropriately.

While the infant formula regulations help ensure the consistent production of safe and nutritionally adequate infant formulas for healthy term infants, they apply with one narrow exception. Section 412(h)(1) of the FD&C Act exempts an infant formula represented and labeled for use by an infant with an inborn error of metabolism, low birth weight, or who otherwise has an unusual medical or dietary problem from the requirements of subsections 412(a), (b), and (c) of the FD&C Act. These formulas are customarily referred to as "exempt infant formulas." Section 412(h)(2) of the FD&C Act authorizes us to establish terms and conditions for the exemption of an infant formula from the requirements of subsections 412(a), (b), and (c) of the FD&C Act.

In support of exempt infant formulas, we have issued the Agency guidance document entitled "Exempt Infant Formula Production: Current Good Manufacturing Practices (CGMPs), Quality Control Procedures, Conduct of Audits, and Records and Reports." The guidance

document includes our recommendation that manufacturers of exempt infant formulas follow, to the extent practicable, subparts A, B, C, D, and F of 21 CFR part 106, and is available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-exempt-infant-formula-production.

We have also developed electronic Form FDA 3978 (Infant Formula Tracking System (IFTRACK)) so that infant formula manufacturers may electronically submit reports and notifications in a standardized format to FDA. However, manufacturers that prefer to submit paper submissions in a format of their own choosing will still have the option to do so. Form FDA 3978 prompts a respondent to include reports and notifications in a standard electronic format and helps the respondent organize their submission to include only the information needed for our review. Screenshots of Form FDA 3978 and instructions are available at https://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/InfantFormula/default.htm.

Description of Respondents: Respondents to this information collection are manufacturers of infant formula.

In the *Federal Register* of December 2, 2020 (85 FR 77469), we published a 60-day notice requesting public comment on the proposed collection of information. Two comments were received providing general comment regarding requirements for infant formula labeling; however, neither comment requested revision to the burden estimates.

We estimate the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden[1]

FD&C Act or 21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Reports; Section 412(d) of the FD&C Act	5	13	65	10	650
Notifications; § 106.120(b)	1	1	1	4	4
Reports for exempt infant formula; § 107.50(b)(3) and (4)	3	2	6	4	24
Notifications for exempt infant formula; § 107.50(e)(2)	1	1	1	4	4
Requirements for quality factors--growth monitoring study exemption; § 106.96(c)	4	9	36	20	720

Requirements for quality factors--Protein Efficiency Ratio exemption; § 106.96(g)	1	34	34	12	408
New infant formula registration; § 106.110	4	9	36	0.50 (30 minutes)	18
New infant formula submission; § 106.120	4	9	36	10	360
Total					2,188

[1] There are no capital or operating and maintenance costs associated with the information collection.

Based on a review of the information collection, we have adjusted our burden estimate to correct a nominal calculation error. This reflects a decrease of 62 annual responses and a corresponding decrease of 308 annual hours.

In compiling these estimates, we consulted our records of the number of infant formula submissions received in the past. All infant formula submissions may be provided to us in electronic format. The hours per response reporting estimates are based on our experience with similar programs and information received from industry.

The total estimated annual reporting burden is 2,188 hours, as shown in table 1.

Table 2.--Estimated Annual Recordkeeping Burden[1, 2]

FD&C Act or 21 CFR Part	No. of Recordkeepers	No. of Records Per Recordkeeper	Total Annual Records	Average Burden Per Recordkeeping	Total Hours
Part 106--subpart B: CGMP Requirements	5	429.8	2,149	4.4	9,414
Part 106--subparts C through G: Quality control; audits; quality factors; records and reports	5	726.8	3,634	6	21,818
Part 107--subpart C; Exempt infant formulas	3	10	30	300	9,000
Exempt infant formula production; GMP; audits, recordkeeping, and reports	3	634	1,902	45	85,590
Total					125,822

[1] There are no capital costs or operating and maintenance costs associated with the information.
[2] Numbers have been rounded.

The total estimated annual recordkeeping burden is 125,822 hours, as shown in table 2.

Table 3.--Estimated Annual Third-Party Disclosure Burden[1]

Activity; 21 CFR Section	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
Nutrient labeling; 107.10(a) and 107.20	5	13	65	8	520

[1] There are no capital costs or operating and maintenance costs associated with the information collection.

We estimate compliance with our infant formula labeling requirements in 21 CFR 107.10(a) and 107.20 requires 520 hours annually.

Dated: April 15, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021-08470 Filed: 4/22/2021 8:45 am; Publication Date: 4/23/2021]